REMARKS

This patent application includes Claims 3-15, 19, 20, 35, 42, 65, 85, 110 and 120-202, all of which stand rejected. Claim 3 has been canceled. Claim 4 has been presently amended to define the applicants' invention more precisely and all rejections are respectfully traversed.

Claims 3-15, 19-20, 35, 40, 65, 85, 110 and 120-202 have been rejected as obvious under 35 U.S.C. §103(a) as being unpatentable over Paltieli, U.S. Patent No. 6,216,981, in view of Schweikard et al., U.S. Patent No. 6,501,981.

The Examiner states that Paltieili teaches the use of transponders on the ultrasonic imager and on the invasive instrument as well as a processor which receives the information from the transponders and computes their positions along with the position and orientation of the ultrasound image plane associated with the imager (Col. 6, line 66 - Col. 7, line 61). The Examiner states that Paltieli further teaches a common coordinate system. The Examiner admits that Paltieli does not teach monitoring the organ-timing signal.

However, the Examiner alleges that Schweikard et al. teach "gating" or "triggering" of an inspected organ monitor interface connected to a processor and to an organ monitor, the organ monitor monitoring an organ timing signal associated with an inspected organ (Fig. 8; Col. 6, lines 51-65; claims 11 and 23). The Examiner notes that this gating or triggering is performed so that accurate treatment is performed compensating for movement of the patient, such as due to respiration. The Examiner alleges that it would have been obvious to one skilled in the art to have modified Paltieli and incorporate the triggering or gating of therapy on the basis of monitoring motion as taught by Schweikard et al. in order to compensate for movement such as respiration, especially when surgical treatment is targeted in an area of interest where there is substantial movement.

On May 23, 2005, the undersigned and Mr. Eliav Korakh, applicant's representative, held a personal interview with the Examiner. During that interview, the pending claims, the Paltieli and Schweikard et al. references, and U.S. Patent No. 5,924,989 to Polz were discussed. Specifically, it was discussed that the combination of features included in claims 3 and 4 was not disclosed in any of the art of record. This combination of features was also stated to be included in

the remaining independent claims. The Examiner agreed to consider carefully the allowability of the claims in light of these arguments but stated that a new search would need to be performed.

The Examiner's present rejection is respectfully traversed. None of the cited references, either alone or in combination, renders these claims obvious.

Paltieli discloses a method and apparatus for free-hand directing of a needle towards a target located in a body volume. The disclosed purpose is to perform needle biopsy, aspiration or injection by accurately guiding the movement of a medical needle as it penetrates the body guided by an ultrasound or other imaging device. The system includes an ultrasound probe 28 including a probe orientation sensor 30 for sensing spatial position data of the probe. The system also includes a needle 12 held fixed in a needle guide 32, further including a needle orientation sensor 34 for sensing spatial orientation data of the needle. Preferably an array of spaced-apart transponders 60, 62 is used for the sensors 30, 34.

An ultrasound system produces an image of the target tissue using the probe 28, and this image is sent to and displayed on a display screen 22. A computer 24 receives data from the sensors 30, 34 and computes the position of the probe 28 and needle guide 32 in relation to an inertial reference. The computer also computes the position and orientation of the ultrasound image plane associated with the probe. The computer then computes the trajectory of the needle in accordance with known geometric formulas, which trajectory is an imaginary straight line emanating from the point of the needle and along its longitudinal axis. The trajectory is displayed on the display screen and the user may then insert the needle towards the target in a guided manner.

The Examiner notes that Paltieli does not disclose monitoring an organ-timing signal. This statement of Paltieli is absolutely correct. Paltieli also discloses a real-time display system. For this reason, Paltieli does not disclose storing two or three dimensional images in a database together with location and orientation information of the imaging transducer and an associated organ timing signal, nor does Paltieli disclose retrieving a stored image having a stored organ timing signal substantially equal to a real time detected organ timing signal. Additionally, Paltieli does not disclose the use of semi-transparent goggles as a display, wherein the goggles further include a

positioning sensor such that the location and orientation of the goggles can be obtained and utilized for the selection of a viewing plane for visual representation of images.

Schweikard et al. disclose an apparatus and method for performing treatment on an internal target region while compensating for breathing and other motion of the patient. Preferably the system is used for compensating for motion during radiation treatment, although other disclosed uses include medical procedures such as positioning biopsy needles, ablative, ultrasound or other focused energy treatments, or positioning a laser beam for laser beam treatment. Specifically, the system alleges to improve efficacy and accuracy of surgical treatment by locating a target region to be treated and tracking the motion of the target region due to respiratory and other patient motions during the treatment. Because radiation treatment is focused on destroying a tumor using a beam of ionizing radiation, which radiation also may damage surrounding healthy tissue, accommodating for patient motion during such treatments is imperative.

The Schweikard et al. system includes a first imaging device for **periodically** generating positional data about one or more markers attached to an internal target region and a second imaging device for **continuously** generating positional data about one or more external markers attached to a patient's body. A set of internal markers 152 is placed on a target organ 151 within a body 150 of the patient. As the target organ moves, the internal markers also move. The internal markers 152 may be imaged using a stereotaxic x-ray or like device, which device permits the precise location of the internal markers to be determined. Because it is necessary to limit a patient's exposure to radiation, these internal markers are imaged only periodically.

However, such periodic imaging is insufficient to illustrate motion due to breathing and other patient activities. For this reason, one or more external markers 180 are also attached to the skin of the patient to permit the motion of the abdomen or chest wall to be determined, such as when the patient inhales and exhales. The external markers are preferably continuously tracked using optical methods, such as infrared or visible light, such that the position of the markers may be determined more than 60 times per second. Of note, the external markers can not alone reflect the internal motion of the target organ since the target organ may move only a small amount while the external markers may move a larger amount, or vice versa. For this reason, a combination of

internal and external markers are disclosed. Additionally, in order to synchronize the motion of the internal and external markers, the system correlates the motion of the external and internal markers to determine a correspondence between them (e.g., external motion = 10 mm along x axis, internal motion = 3 mm along x axis).

Once the correspondence between the internal and external marker movement is determined, the system can use the continuous tracking of the external markers, supplemented by periodic tracking of the internal markers, to determine the location of the internal target region at all times, regardless of the patient's motion. Schweikard et al. further disclose gating the treatment in response to the correspondence between the internal and external motions, so that the treatment is switched on when the target region is in a desired position, and switched off when the target region is not in a desired position.

Like Paltieli, Schweikard et al. is directed to a real-time treatment system. For this reason, Schweikard et al. do not disclose storing two or three dimensional images in a database together with location and orientation information of the imaging transducer and associated organ timing signals, nor do they disclose retrieving a stored image having a stored organ timing signal substantially equal to a real time detected organ timing signal. Additionally, Schweikard et al. use the organ timing signal for correcting position and orientation readings; they do not use the organ timing signal to synchronize pseudo real-time visualization. Schweikard et al. also do not disclose the use of semi-transparent goggles as a display, wherein the goggles further include a positioning sensor such that the location and orientation of the goggles can be obtained and utilized for the selection of a viewing plane for visual representation of images. Further, Schweikard et al. do not disclose a medical positioning system having a transducer with a tracking sensor for determining the transducer's location and orientation, a surgical tool with a tracking sensor for determining the surgical tool's location and orientation, or an image which is correlated with both an organ timing signal received from an organ monitor interface at the time the image was taken and the location and orientation information of the imaging transducer at the time the image was taken.

Neither Paltieli, Schweikard et al., nor the combination of the two disclose the invention claimed in the present application. The present invention is directed to a medical imaging and

navigation system including a processor, a display unit, a database, a medical positioning system, a two-dimensional imaging system, an inspected organ monitor interface and a superimposing processor. The medical positioning system includes an image detector having a sensor and a surgical tool including a sensor. At least a third sensor is placed on the body of the patient for reference. The inspected organ monitor interface is connected to an organ monitor which monitors an organ timing signal associated with an inspected organ. The organ timing signal is used to synchronize the pseudo real-time visualization.

The present system acquires two-dimensional images using the image detector and records each image in association with the detected location and orientation information (as determined by its sensor), and with the organ timing signal reading (as detected by the organ monitor). The organ timing signal is assumed to be cyclic such that a reading in one cycle will be repeated in a subsequent cycle. A three-dimensional image can be reconstructed from all the recorded two-dimensional images having the same organ timing signal reading (from different cycles). For example, if the organ timing signal is a cyclic ECG signal, the two-dimensional images can be synchronized by grouping together all images taken at a predetermined position in the organ timing signal (see Figs. 4, 5a, 5b, 5c). Thus, if four images are taken each ECG cycle and if this cycle repeats continuously, the images taken at the first cycle would comprise images 1-4, the images at the second cycle would comprise images 5-8 and the images at the third cycle would comprise images 9-12. Images 1, 5 and 9 could be grouped together; images 2, 6 and 10 could be grouped together; images 3, 7 and 11 could be grouped together; and images 4, 8 and 12 could be grouped together. These images would then represent the same activity state within each cycle, thereby creating a group of two-dimensional images associated with that particular activity state. A three-dimensional representation can then be created and associated with each of the activity states.

A sequence of these images can be displayed, synchronized with a real-time reading of the organ timing signal, thereby providing a pseudo real-time visualization of the inspected organ. Additionally, a surgical tool can be inserted into the body of the patient, the location and orientation of which can be detected by the sensor. In this way, an image of the surgical tool can be superimposed on the displayed image (i.e., the pseudo real-time visualization) of the organ.

Independent apparatus claim 4 (and claims 5-15 and 123-125 depending therefrom) provides for an inspected organ monitor interface monitoring an organ timing signal associated with an inspected organ. The organ timing signal is detected for each of a plurality of two-dimensional images and associated with the corresponding image. Further, each two-dimensional image is stored in a database together with its respective timing signal. Finally, a real time detected organ timing signal is obtained and a processor selects at least one stored two-dimensional image having a stored organ timing signal substantially equal to the real time detected organ timing signal.

Independent apparatus claim 35 (and claims 126-136 depending therefrom) provides for a database including images of an inspected organ, wherein each image is associated with an organ timing signal as determined by the organ monitor interface at the time of the image. Claim 35 further provides for obtaining a real-time detected organ signal, wherein the processor selects one or more images from the database having a stored organ timing signal substantially equal to the real-time detected organ timing signal. Claim 35 additionally provides for a display comprising semi-transparent goggles, the goggles including a sensor such that the processor selects a viewing plane for display of images according to the location and orientation information received from the goggles sensor.

Independent method claim 42 (and claims 137-156 depending therefrom) provides for the steps of: (a) detecting an organ timing signal of an inspected organ; (b) detecting a plurality of two-dimensional images of an inspected organ; (c) associating each of the two-dimensional images with the detected organ timing signal; (d) reconstructing a plurality of three-dimensional images based on the two-dimensional images, where the utilized two-dimensional images are selected based on their position within an organ timing cycle; (e) obtaining a real-time organ timing signal; (f) selecting a three-dimensional image based on the real-time signal; and (g) displaying the three-dimensional image.

Independent method claim 65 (and claims 164-172 depending therefrom) provides for the steps of: (a) detecting a plurality of two-dimensional images of an inspected organ; (b) obtaining an organ timing signal for each of the two-dimensional images and associating each of the two-

dimensional images with the timing signal; (c) reconstructing a plurality of three-dimensional images from the two-dimensional images, the three-dimensional images corresponding to two-dimensional images having a selected position within an organ timing cycle; (d) detecting a real-time organ timing signal of the inspected organ; and (e) selecting a previously stored three-dimensional image corresponding to the real-time signal.

Independent method claim 85 (and claims 173-187 depending therefrom) provides for the steps of: (a) detecting a plurality of two-dimensional images of an inspected organ; (b) obtaining an organ timing signal corresponding to each of the two-dimensional images and associating each two-dimensional image with its respective organ timing signal; (c) reconstructing a plurality of three-dimensional images, each corresponding to two-dimensional images reflecting a selected position within an organ timing cycle; (d) detecting a real-time organ timing signal of the inspected organ; and (e) selecting a previously stored three-dimensional image corresponding to the real-time signal. The claim also provides for the steps of detecting the location and orientation of the point of view of the user and rendering the selected three-dimensional image based on the detected location and orientation.

Independent method claim 110 (and claims 188-202 depending therefrom) provides for the steps of: (a) detecting a real-time organ timing signal of an inspected organ; and (b) selecting a previously stored two-dimensional image having an associated stored organ timing signal corresponding to the real-time signal. Thus, this claim requires that a two-dimensional image has been previously obtained with an associated organ timing signal obtained at the time of the image, and stored therewith.

Thus, each of the present claims provides for a system or method wherein a two-dimensional image of an inspected organ is obtained, an organ timing signal corresponding to the time the image was taken is obtained, and the image and its respective organ timing signal are associated with one another. Each of the claims further provides for storage of the image together with its associated timing signal. Finally, each of the claims provides for obtaining a real-time organ timing signal and selecting and/or displaying a stored two or three dimensional image having

a stored timing signal corresponding to the real-time timing signal. These features are not disclose in any of the art of record, either alone or in combination with one another. For this reason, all of the independent claims present in this application are in condition for allowance. The dependent claims are allowable, at least owing to their dependence from an allowable claim

Applicants' attorney has made every effort to place this patent application in condition for allowance. It is therefore requested that the present amendment be entered, that this application as a whole receive favorable reconsideration, and that all of the claims be allowed as presently constituted. Should there remain any unanswered questions, the Examiner is requested to call the Applicants' undersigned attorney at the telephone indicated below.

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Respectfully submitted,

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